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Dear Secretary Fielder,

Thank you for the opportunity to respond to the University of Maryland Baltimore (UMB) School of Pharmacy's objection to MUIH's Post-Baccalaureate Certificate (PBC) in Cannabis Science: Therapeutics, Product Design, and Quality Assurance. We disagree with the conclusions drawn by UMB on the following grounds.

Concerning unreasonable program duplication, the two programs have different structures and emphases. MUIH's program is a post-baccalaureate certificate that emphasizes a health and wellness perspective on cannabis in the context of traditional herbal medicine. UMB's program is a master's of science degree that emphasizes a medical (i.e., disease treatment and management) perspective on cannabis in the context of conventional pharmaceutical sciences.

Regarding a competitive target audience, there is an enormous market need for education in the rapidly growing field of cannabis science. There are currently only five U.S. universities offering graduate programs focused on the multi-billion dollar cannabis industry, and none of the programs, including the UMB program, target integrative health professionals or students interested in incorporating the principles and practices of herbal medicine into cannabis product design.

We also question UMB's claim that two of MUIH's proposed courses represent inconsistent allowable content between the institutions' programs. However, we have modified the relevant course titles and descriptions to address any possible conflict.

Each of UMB's specific concerns is addressed in detail below.

## 1. Unreasonable Program Duplication

#### a. Program Structure and Emphases

The MUIH and UMB programs have very different structures. MUIH's program is a 15-credit Post-Baccalaureate Certificate. UMB's program is a 30-credit Master of Science. The contents of the two programs overlap in foundational content areas, but differ significantly in the segments of the cannabis industry on which they focus, the unique strengths of the two universities, and the learning opportunities they provide for students interested in studying cannabis.

The cannabis field can be approached and viewed through a variety of lenses. MUIH's program approaches cannabis through two primary lenses: 1) health and wellness, and 2) herbal medicine. Our analysis suggests that UMB's program approaches cannabis through two distinctly different primary lenses: 1) medicine, and 2) a conventional pharmacy orientation. These differing approaches are

described in more detail below. In addition, while they possess some common words, other key words point to the differences between these two programs:

		Common Terms	Different Terms
MUIH	PBC Cannabis Science: Therapeutics,	Cannabis	Product Design
	Product Design, Quality Assurance	Science	Quality Assurance
UMB	MS Medical Cannabis Science and	Therapeutics	Medical
	Therapeutics		Medical

MUIH based the comparative analysis of its program on that of UMB in its original proposal and this response on UMB's existing M.S. program. It is our understanding that the criteria for allowable objections include existing programs and program proposals that are in MHEC's public review and comment phase and do not extend to programs that have not yet been submitted to MHEC for approval, such as the three graduate certificates in medical cannabis that UMB is planning to submit. We do not yet see these proposals reflected on MHEC's website.

## b. Health and Wellness Focus

UMB claims that, MUIH's "program and courses are titled to suggest a specific focus on medical cannabis that is similar to our UMB program."

MUIH's program and courses discuss cannabis in general, not just medical cannabis. Medical cannabis, the focus of the UMB program, is used within a conventional healthcare model to help treat and manage disease. While medical cannabis is reviewed in the MUIH program, there is additional emphasis on non-medical, CBD-dominant types of cannabis. These federally legal, non-psychoactive forms of cannabis are increasingly incorporated into health and wellness models of care. Such models are less focused on disease management and more focused on supporting health-positive constructs such as resilience and well-being.

This health and wellness focus is consistent throughout all of MUIH's programs and distinguishes them from more conventional healthcare programs.

### c. Herbal Medicine Focus

UMB notes, "The MUIH proposal states that what makes their content unique is the 'overarching focus on herbal medicine.' However the program and courses are titled to suggest a specific focus on medical cannabis that is similar to our UMB program."

MUIH wishes to first clarify that an "overarching focus on herbal medicine" is only one of seven differentiators that clarify the uniqueness of the MUIH program and how it is differentiated from the UMB program. The relevant table from Section D of the original submission is included below.

Content Similarities	Unique to UMSOP	Unique to MUIH Program	
<ul> <li>Cannabinoid chemistry and pharmacology</li> <li>Clinical effects of medical cannabis</li> <li>Therapeutics and known side effects</li> </ul>	<ul> <li>Introduction to medical cannabis history and culture</li> <li>Broad view of cannabis laws and policies</li> </ul>	<ul> <li>Overarching focus on herbal medicine</li> <li>Therapeutic focus on both health promotion and disease management</li> <li>Therapeutic strategies that combine cannabis with herbal medicine</li> </ul>	

- Research design and medical cannabis.
- Cannabis genomics
- Advanced cannabinoid chemistry and analytic testing methodology
- Formulation and designing herbal/cannabis products
- Regulatory and good manufacturing practices in the herbal supplement market
- Focus on dispensary function, services, and related state and federal cannabis laws and policies
- Focus on all 3 market segments – CBD dominant chemovars that make up the herbal supplement domain, and the medical and recreational use of THC dominant chemovars

With respect to UMB's stated concern, MUIH wishes to clarify that cannabis is discussed within the broader context of herbal medicine as a whole, a significant distinction from the UMB program. Two key aspects of traditional herbal medicine are worth noting here. First, herbs are not typically used alone and are mostly used as part of combination formulas. While cannabis may be the central herb addressed in the MUIH program, there will be a continual discussion and consideration of other herbs that can be combined to potentially enhance benefits and reduce risk. Second, herbal medicine emphasizes different categories of herbs and clinical approaches for "compensation" (support during illness and dysfunction) and "enhancement" (support for building and maintaining healthy function). This offers an additional lens through which to view cannabis and provides further contrast between a medical model and a health and wellness model. MUIH did not identify any discussion of the broad field of herbal medicine or the use of other herbs in UMB's program.

MUIH has long-standing expertise in herbal medicine and is one of the very few accredited universities in the U.S. to offer graduate programs in the field. MUIH has delivered master's programs in herbal medicine since 2002, when it launched the first master's degree in herbal medicine in the United States. MUIH plans to offer the PBC in Cannabis Science through the Department of Nutrition and Herbal Medicine. The faculty in herbal medicine understand cannabis as one of many therapeutic plants and this perspective will permeate all aspects of the program. They are uniquely qualified to discuss cannabis within the framework of general herbal medicine principles and practices, something quite distinct from a conventional pharmacy perspective. This differentiation is addressed further in the discussion of the individual courses below.

## d. Course Comparisons

UMB states, "Four of the six courses in MUIH's program are extremely similar in content to courses and content taught in our program at UMB, teaching the endocannabinoid system, cannabis therapeutics, product formulation, and academic research."

Regardless of their unique focus, any two programs in cannabis might be expected to share some foundational content upon which to build more advanced and differentiated skills and knowledge. This principle is widely seen in academia and across disciplines; for example, general business administration programs all share foundational courses in management, marketing, and finance. With respect to cannabis programs, the endocannabinoid system and therapeutics are considered foundational

knowledge and skills and would naturally be included in most such programs. In fact, five of the six other graduate cannabis programs currently offered in the US also offer foundational coursework in the endocannabinoid system and therapeutics.

The four MUIH courses that UMB refers to are, MUIH550 Academic Research and Scholarship; HRB610 The Endocannabinoid System and Phytocannabinoids; HRB611 Cannabis Therapeutics; and HRB613Formulating Herbal Products using Cannabis. A closer analysis of these courses makes it clear that there are significant differences from the UMB content, as summarized in the following table and detailed in the course-by-course comparisons below.

MUIH Course	UMB Course	Extent of Overlap
MUIH550	MCST611	No overlap
HRB610	MCST602 & MCST604	Some overlap
HRB611	MCST604	Some overlap
HRB613	MCST 603	Insignificant overlap

#### MUIH550 Academic Research and Scholarship

This is a non-credit course conducted by the Sherman Cohn Library at MUIH. Modules cover the Association of College and Research Libraries information literacy threshold concepts in higher education; these concepts are scholarship as conversation, research as inquiry, authority is constructed and contextual, information creation as a process, searching as strategic exploration, and information has value. MUIH550 is a basic background course that helps students find and utilize information in academic libraries. It is required of all students in all programs during their first trimester. The course content is comprised solely of information literacy concepts. The course content does not include cannabis.

MUIH550 bears no resemblance to the UMB research course (MCST 611 Research Design and Medical Cannabis). The UMB course appears to teach students to develop a pilot project in medical cannabis and create a research proposal "suitable for submission to an institutional review board." Designing and conducting research studies is entirely different from information literacy. The UMB course description also notes, "students will also learn how to critically evaluate medical and scientific evidence." Again, this is quite distinct from basic library science information literacy as taught in MUIH550.

We therefore see no overlap or conflict between MUIH's MUIH550 and UMB's MSCT 611. The true equivalent MUIH courses to MCST 611 might be RSCH601 Introduction to Research Literacy and RSCH821 Designing Research in Clinical Practice. Neither of these courses is included in the PBC Cannabis Science.

#### HRB610 The Endocannabinoid System and Phytocannabinoids

This course introduces the endocannabinoid system as a regulator of biological functions in health and disease. Having the first course in the PMC focus on the body's own biological system, as opposed to cannabis, is intentional and distinct from UMB's program and courses. Emphasizing study of the endocannabinoid system facilitates an understanding of the primary mechanisms through which cannabis has its effects, and also opens up discussion of other (non-cannabis) phytocannabinoid-containing herbs (e.g., Echinacea) and lifestyle factors (e.g. exercise) that impact health through this system. In addition, the focus on the regulatory role of the endocannabinoid system allows for discussion of the system's impact on health and wellness concepts such as resilience. This approach

aligns with MUIH's holistic and integrative focus and differentiates it from the UMB program's focus on medical cannabis and medical application.

In reviewing the potential overlap of coursework between the two programs, no specific mention of the endocannabinoid system could be found in UMB's program description, course titles, or course descriptions. There was also no mention of phytocannabinoids from plants other than cannabis. It is assumed that some aspects of the endocannabinoid system are covered in courses such as MCST 602: Principles of Drug Action and Cannabinoid Pharmacology and MCST 604: The Clinical Effects of Medical Cannabis, since knowledge of the endocannabinoid system is necessary to understand how cannabis has its effects. However, the lack of any centralized course on the endocannabinoid system, or even mention of the endocannabinoid system in the UMB course descriptions, suggests that the MUIH course, HRB610 The Endocannabinoid System and Phytocannabinoids, is more of a program differentiator than evidence of significantly overlapping content.

#### HRB611 Cannabis Therapeutics

This course addresses the evidence base for cannabis as a therapeutic intervention for disease and illness and as a tool for promoting health and well-being. While it does review the literature on the use of medical cannabis, it also discusses the emerging evidence for CBD-dominant (non-psychoactive) forms of cannabis marketed in the health and wellness arena. While the course description does not mention that cannabis interventions will be discussed in the context of other therapeutic herbs, this is a consistent theme in the program and is stated more explicitly in the description for HRB613 Formulating Herbal Products Using Cannabis (see discussion below). MUIH can modify the course description to specifically state this aspect which was already planned as a course topic.

HRB611 Cannabis Therapeutics is arguably the one course in the MUIH PBC that shares significant content with the UMB program. Like HRB611, UMB's MCST 604: The Clinical Effects of Medical Cannabis, as well as the electives in "Advanced Cannabis Therapeutics", focus on the evidence base and use of cannabis as a therapeutic tool. Despite the similarities, there are some significant differences. The UMB course descriptions focus on the use of cannabis for disease states and health disorders. This is appropriate given the UMB program's focus on medical cannabis and medical applications. Unlike the MUIH coursework, nothing in the UMB course descriptions suggests any discussion of CBD-dominant (non-psychoactive) forms of cannabis sold for non-medical reasons and used to support health and wellness. There is also no mention of complementing the use of cannabis with other therapeutic herbs. These distinctions between the two programs continue from HRB610 and represent a central theme that is most evident in the next course, HRB 613.

#### HRB613 Formulating Herbal Products using Cannabis

This course leverages MUIH's expertise in herbal medicine to explore opportunities to optimize cannabis' benefits and reduce risks by combining cannabis with other medicinal plants. Students learn to formulate a cannabis-containing multi-herb blend for a specific purpose and to explain the rationale behind the product. Emphasis is placed on designing CBD-dominant, hemp-based dietary supplements and wellness products (as opposed to medical cannabis products).

HRB 613 encapsulates some of the key differences between MUIH's proposed PBC and UMB's program. First, the course's primary focus is exploring strategies for incorporating cannabis as one component of a larger herbal formula that includes multiple herbs. This topic does not seem to be addressed anywhere in the UMB program. Second, the course emphasizes product design using CBD-dominant (non-psychoactive) cannabis for the dietary supplement and wellness product market. Such products are available through a number of retail avenues, including natural food stores, and represent a

completely different market than the medical cannabis products that are the focus of the UMB program, and which are restricted to distribution through medical cannabis dispensaries.

There does not seem to be any significant overlap between HRB 613 and the UMB program content. The closest material may be in MCST 603: Basic Cannabinoid Chemistry and Drug Delivery. The course description notes, "This course also introduces students to the science of designing dosage forms. Topics include the formulation, development, evaluation, selection and administration of safe, effective, reliable, drug delivery systems, with a focus on development of medical cannabis products. The wide variety of cannabis delivery systems and routes of delivery and the impact of those delivery systems have on the bioavailability of cannabis will be evaluated in this course."

While both HRB 613 and MCST 603 mention "formulating" or "formulation" with cannabis, the term has two distinct meanings. In the context of conventional pharmacy (UMB's program), formulation typically refers to ways to optimize the effectiveness and acceptability of a drug (e.g., cannabis) by combining it with various inactive substances and developing different dosage forms (e.g., capsules, topical applications). In the context of herbal medicine (MUIH's program), formulation usually refers to optimizing benefits by combining a number of therapeutic, active herbs into a multi-herb blend (e.g., combining cannabis with Echinacea). Both approaches to "formulation" have value for enhancing the benefits of cannabis, but they represent two different theoretical and practical strategies that speak to the complementary but distinct foci of the UMB and MUIH programs.

In summary, while there are some superficial similarities between the courses in the two programs, a closer look at the courses themselves reveals unique programs that speak to the different segments of the cannabis industry, the unique strengths of the two universities, and provide different content learning opportunities for students interested in studying cannabis.

# 2. Competitive Target Audience

#### a. Market Need

The herbal medicine and cannabis sectors are experiencing rapid growth and are projected to have continued significant growth into the future. In the herbal medicine sector, more than 40 million individuals in the U.S. used non-vitamin, non-mineral supplements in 2012, up from 38 million users in 2007. In 2017, total U.S. retail sales of herbal supplements surpassed \$8 billion for the first time, reaching nearly \$8.1 billion. Total U.S. retail sales of herbal supplements have increased every year since 2004, and since that time consumer spending on supplements has nearly doubled. In the cannabis sector, total combined U.S. legal sales are projected to continue to grow at an annual rate of 14%, reaching \$30 billion in sales by 2025. Globally, the cannabis market (including medical, recreational and hemp-based) was \$10.6 billion in 2018 and is projected to reach \$97.3 billion by the end of 2026. The number of full-time workers in the U.S. marijuana industry was between 130,000 and 160,000 in 2018 and increased to 175,000 to 215,000 in 2019. These numbers are projected to reach 385,000 to 475,000 workers by 2023, and 630,000 cannabis jobs by 2025. (Additional information on the growth of the herbal medicine and cannabis fields and jobs is provided in MUIH's original proposal to MHEC.)

However, there are only five universities in the U.S. offering graduate programs to support the need for academic and scientific rigor and a focus on setting safe and quality standards in this emergent field. Three other universities offer programs very similar to UMB's program with a focus on medical cannabis: Thomas Jefferson University (PA), Pacific College of Health and Science (CA), and American International College (MA). One of these programs is offered online and the other four programs are offered in the hybrid format. These programs are summarized in the following chart.

Level	Institution	Program	Format
Graduate	Jefferson University (PA)	Certificate – Cannabinoid Chemistry and Toxicology	Hybrid
		Certificate – Cannabinoid Pharmacology	Online
		Certificate – Cannabis Medicine	Online
	University of Maryland, School of Pharmacy (MD)	MS Medical Cannabis and Therapeutics	Hybrid
	Clark University (MA)	Certificate – Regulatory Affairs for Cannabis Control	Online
	Pacific College of Health and Science (CA)	Certificate – Medical Cannabis for Healthcare Professionals	F2F
	American International College (MA)	MS Cannabis Science and Commerce	Hybrid
Undergraduate	Hocking College (OH)	AAS Laboratory Science – Cannabis Lab Technician	F2F
	Minot State Univ (ND)	BS Medicinal Plant Chemistry (cannabis concentration)	F2F
	Northern Michigan Univ (MI)	BS Medicinal Plant Chemistry (cannabis concentration)	F2F
	Oakton Community College (IL)	Certificate – Cannabis Dispensary & Patient Care Specialist	F2F
	Western Illinois University (IL)	Minor – Cannabis-Growing	F2F

MUIH asserts that in the face of such national growth of the cannabis field, five universities are not sufficient to support the educational needs of the various segments of this field. MUIH is well positioned to become the sixth university in the U.S. to support this field, not only because of its distinct focus but also because of the overall growth in interest in cannabis in health fields.

MUIH has been delivering online programs since 2013. Of its 22 programs, 13 are offered in the online format and seven are offered in the hybrid format. 69% of students are enrolled exclusively in online courses and 23% take a mix of online and face-to-face courses. MUIH has also developed a national presence and following for its programs; students are enrolled from 43 states, the District of Columbia, and internationally. MUIH asserts that in the face of a robust national need, and a paucity of relevant programs, preventing it from offering the PBC Cannabis Science program will harm the institution's potential, ability to grow, and ability to achieve its unique mission. This potential harm is amplified when considering MUIH's role as one of only six universities nationally to focus solely on integrative health, its recognized national reputation in the field of herbal medicine, and its demonstrated ability to successfully deliver online programs to individuals across the U.S.

#### b. Target Audience

MUIH views the primary target audience for these programs to be distinctly different. MUIH's program is designed for individuals who wish to promote evidence-informed, safe, and responsible use of high-quality cannabis-based products, especially those with holistic approach and a focus on a health promotion model rather than a disease management model. The program is ideal for those seeking an initial career in the cannabis industry or looking to expand their job options within the field. The program is also designed for conventional and integrative health practitioners interested in learning about cannabis in order to be informed for their clients. UMB notes that their primary audience includes "health

professionals, scientists, public health professionals, business professionals, and others with a stated interest in a career medical cannabis industry." The same differences in program design translate to the primary audiences of the two programs – career starters and integrative health professionals (MUIH) as compared to medical, scientific, public health, and business professionals (UMB). These programs are also distinctly different in an additional way – individuals seeking a deep scientific, pharmacologic, medical, and research approach to cannabis will find what they are looking for in UMB's 30 credit master's program and not in MUIH's 15 credit post-baccalaureate certificate program.

Both programs prepare individuals to enter the growing cannabis industry, albeit in different ways. MUIH's program focuses on preparation for herbal product design, herbal dispensary (see below), and hemp and CBD aspects of the industry. In contrast, UMB's program appears to focus on preparation for the medical cannabis aspects of the industry.

Both programs are designed for individuals who have little to no science background. This is an intentional design element for all of MUIH's programs. Pre-requisite knowledge, skills, and courses are built into the first-year curriculum of all programs, and with very few exceptions no prerequisite knowledge or credentials in the field are required for admission to MUIH's programs. The existing science-based graduate programs in nutrition and herbal medicine routinely admit new students with little to no experience in these fields, and the pre-requisite science knowledge and skills are imparted through specific courses or basic concepts intentionally woven through the curriculum. This design element is consistent to MUIH's overall philosophy of curriculum design and is not specific to the proposed cannabis program.

#### 3. Inconsistent Allowable Content

MUIH wishes to clarify that "dispensary" in its PBC program incorporates principles and practices of herbal dispensaries in general, not just those of medical cannabis dispensaries. MUIH has had a functioning herbal dispensary since 2002 when it launched the first master's degree in herbal medicine in the United States. For 18 years, the dispensary has served as an educational setting for dispensary practices and quality assurance while providing herbal products to healthcare professionals, herbal medicine students, and the general public. This dispensary does not work with cannabis products and it is not a medical cannabis dispensary. It was always MUIH's intention that the standards and practices from its herbal dispensary, generalizable to working with a range of herbs for various health and wellness purposes in various settings, would be leveraged to inform the HRB612 Cannabis Dispensary Practices and HRB614 Quality Assurance in Cannabis Products courses.

As UMB notes, the HRB612 Cannabis Dispensary Practices and HRB614 Quality Assurance in Cannabis Products courses are unique to the MUIH program. These courses add to the ways in which the MUIH program differs from the UMB offering. Out of an abundance of caution regarding federal law, and to avoid the appearance of offering coursework not allowable for the UMB program, we have slightly modified the course titles and descriptions below to clarify the intent to address herbal dispensary practices and quality assurance for federally legal, non-psychoactive, CBD-dominant cannabis products and herbal products in general. To address UMB's concern about inconsistent allowable content, the course titles and descriptions have been adjusted to clarify that the courses speak to generic herbal dispensary practices and quality assurance. Cannabis-specific discussion will be limited to federally legal CBD-dominant products.

These changes ensure that there is consistent allowable content between the MUIH and UMB programs while maintaining important program distinctions for the target audiences. The clarified course titles and descriptions are as follows:

# HRB612 Cannabis and Herbal Dispensary Practices

This course addresses federally legal CBD-dominant cannabis products within the context of a good manufacturing practice (GMP) compliant herbal product dispensary. Learn best practices in dispensary operations to provide a range of safe and effective high-quality herbal and cannabis-based supplements to meet community needs. Grounded in the range of federal and state laws, use an ethical and legal framework to communicate professionally about cannabis and other medicinal plants, and to help individuals identify preferred products.

### HRB614 Quality Assurance in Cannabis and Herbal Products

Identify and evaluate the authenticity and quality of raw material from federally legal types of cannabis and other medicinal plants. Interpret assays and specification sheets required to produce good manufacturing practice (GMP) compliant products. Learn to apply procedures associated with GMP compliant manufacturing and dispensary function to ensure the purity, strength, composition and to prevent adulteration of products.

MUIH respectfully submits that there are significant differences in the emphases, content, and target audience of MUIH's PBC Cannabis Science: Therapeutics, Product Design, and Quality Assurance program and UMB's M.S. Medical Cannabis Science and Therapeutics program. These differences support our proposal for this Post-Baccalaureate Certificate and its potential in the growing field of cannabis and health.

Sincerely,

Marc Levin

President and CEO

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